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10/533,251

04/29/2005

Jan Peter Sternby

05049.0002

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22852

7590

11/29/2007

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

11/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/533,251 | <b>Applicant(s)</b><br>STERNBY, JAN PETER |  |
|                              | <b>Examiner</b><br>Leslie R. Deak    | <b>Art Unit</b><br>3761                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12 and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/19/07</u> <u>7/17/07</u> <i>JA</i> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 12 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicant is attempting to claim a device comprising a computer readable medium, but claims the step of "instructions executed by the computer" within the device claim. The cited language indicates that applicant is attempting to protect two statutory categories of invention, device and method, within a single claim.

3. Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). While applicant has added a step to the claimed method, applicant has not actually claimed what the step comprises. Merely repeating the step cited in the preamble does not constitute a valid method step. Accordingly, the claim remains non-statutory.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

6. Claim 17 provides for the use of a device capable of performing certain calculations, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. While applicant has added a step to the claimed method, applicant has not actually claimed what the step comprises. The language added by applicant does not recite any active, positive steps that illustrate how the method is performed. Accordingly, the claim remains indefinite.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-10, 12, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/55166 to Sternby.

In the specification and figures, Sternby discloses the method as claimed by applicant. With regard to claim 1, Sternby discloses a method of estimating the efficiency of a dialysis treatment that comprises the steps of determining the effective

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clearance of the dialyser (see p 22, lines 10-20) as well as determining the whole body clearance (see p 10, lines 17-30) in calculating dialysis efficiency.

With regard to claims 2-4, Sternby discloses a that the prior art uses a method of determining dialyzer clearance comprising the steps of measuring a blood urea concentration immediately at the end of treatment (which is interpreted by the examiner to be within the "approximately" one minute time frame), as well as 30-60 minutes after treatment, which is interpreted by the examiner to encompass applicant's claimed "no earlier than...one half hour after the end of treatment" (see p 10).

With regard to claim 5, Sternby discloses the steps of taking a urea measurement at time zero, taking several other urea measurements after a 60 minute waiting period, deriving a starting urea concentration  $m_0$  based on the measured values, and then dividing starting urea concentration  $m_0$  by the measured blood concentration  $C_b$  (see p 17-19).

With regard to claims 6-8, Sternby discloses the steps of using a removal rate slope to determine whole body clearance or total urea removal (see p19, paragraphs 2-4). Sternby further discloses the use of the slope of  $K/V$ , based on the logarithm of the urea concentration (which is determined from the removal rate) to determine parameters relating to treatment efficiency, or whole body clearance (see p 16-17).

With regard to claims 9-10 and 16, Sternby discloses that these operations may be carried out on a standard hemodialysis system that is capable of measuring urea concentration on the blood side ( $C_b$ ) or the dialysate side ( $C_d$ ) of the device (see p 6-9) and is capable of estimating a whole body clearance ratio as claimed by applicant.

With regard to claims 12 and 14, Sternby discloses that the dialysis apparatus and urea monitor are controlled by computer 17. Since computer 17 operates the in the method claimed by applicant, the computer necessarily comprises the method claimed by applicant encoded on a computer readable medium so that the computer can execute the commands of the disclosed method. Therefore, the Sternby disclosure meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/55166 to Sternby in view of US 6,284,141 to Shaldon.

In the specification and figures, Sternby discloses the method substantially as claimed by applicant, including the steps of performing dialysis under a first set of conditions and analyzing that set of conditions to determine a particular result, which is affected by the operating parameters of the dialysis procedure. Sternby does not specifically disclose the step of performing dialysis again under a second set of conditions. However, Shaldon discloses a method of performing a blood treatment procedure under a first set of efficiency conditions and calculating efficiency while performing the operation. Once the first operation is finished, the method comprises the

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steps of performing the blood treatment procedure under a second set of conditions if necessary. This allows for two sessions of varying intensity to increase patient comfort (see Shaldon columns 1-4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the calculations and method disclosed by Sternby to create and perform two discrete treatment sessions as disclosed by Shaldon in order to provide sessions of differing efficiency, increasing patient comfort, as taught by Shaldon.

### ***Response to Arguments***

11. Applicant's amendment and arguments filed 19 September 2007 have been entered and fully considered.

12. Applicant's arguments with regard to the 35 USC 102 rejection over Keshaviah have been fully considered and are persuasive. The rejections over Keshaviah have been withdrawn.

13. Applicant's arguments with regard to the 35 USC 102 and 103 rejections over Sternby have been fully considered but they are not persuasive.

14. Applicant's argues that the Sternby reference fails to disclose the method and apparatus claimed by applicant, but merely recites the text of the claim against the cited art. Such arguments amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. The arguments fail to make it clear to the Examiner how, exactly, the prior art differs from the claimed invention, since applicant

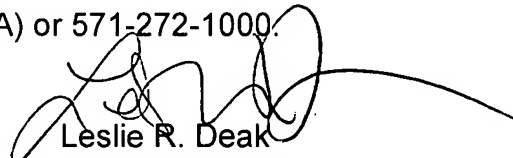
did not explain how the steps disclosed by the prior art do not correspond with the steps claimed by applicant.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
15 November 2007